



PFIZER PGM
ZONE INDUSTRIELLE
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Certificate of Analysis

Material Name: ANTIROBE HARD CAPSULES 150MG B80 HUN
Material Code: 2237HUN

Lot Number: A394704
Specification: 12RS80315(09-02-2006)
Date of Manufacture: OCT. 10, 2013
Expiration Date: SEP-2018

TEST Description	Limit	Result
Identification HPLC (Clindamycin)	Retention time similar to the standard	MEETS TEST
Water content (KF)	7.0% maximum	5.1 %
Average weight	407 - 473mg	440 mg
Identified impurities each	2.0% maximum	0.5 %
Unidentified impurities each	2.0% maximum	0.2 %
Total related impurities	4.5% maximum	1.3 %
Dissolution rate	The requirements are met if the quantities of active ingredient dissolved after 30 minutes conform to the acceptance table below where Q=75%. Continue testing through the three stages unless the results conform either Stage 1 or Stage 2. The quantity Q is the amount dissolved expressed as a percentage of label claim. Stage S1 Number Tested 6 Acceptance Criteria : Each unit is not less than Q+5%. Stage S2 Number Tested 6 Acceptance Criteria : Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15%. Stage S3 Number Tested 12 Acceptance Criteria : Average of 24 units (S1+S2+S3) is equal or greater than Q, and not more than 2 units are less than Q-15% and no unit is less than Q-25%.	99 %
Assay of Clindamycin	95% - 105% of label claim	102 %
Content uniformity	MEETS TEST	MEETS TEST

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP

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Node: emaedca059

Instance Name: LICRFR8P

Diszpó: PN-ZA14000081 Vevő: Alpha-Vet 8000 File név: PN00007701 Egyedi sorszám: PN0000070465 4 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0002/14
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2014.01.30
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.02

